

## REMARKS

### General

An interview was had with the Examiner on October 9, 2009, the courtesy of which is appreciated by the Applicant. In the interview, Applicant was asked to limit the claims to the elected invention. The foregoing amendments to the claims are meant to comply with this request.

### Section 103 Rejections

Claims 1-3 and 5-7 are rejected under 35 U.S.C. Section 103(a) as being unpatentable over Qian et al., Effreth et al., Zheng et al., Venugopalan et al, and Li et al., and further in view of Crooks et al. This ground of rejection is respectfully traversed. This rejection is the same as the last rejection and Applicant reasserts it response filed February 9, 2009. The following additional remarks are made.

#### Crooks, Efferth and Romero

The Crooks patent describes novel compounds and makes the unsupported assertion that these compounds may have activity against hepatitis C. At, column 20, lines 18+, states that the novel compounds stimulate interferon alpha activity as cytokine inducers, similar to interferon or ribavarin. However, the Efferth and Romero articles teach that the activity of a compound of the present invention, namely artemisinin, is most likely not as a cytokine inducer because of the additive effect observed when used together with interferon or ribavarin. Accordingly, the Crooks reference is not effective prior art against the present claims as the activity of artemisinin is completely different from the activity of the compounds described in Crooks. Reconsideration and withdrawal of this ground of rejection is respectfully requested.

#### Method of Testing Used in the Present Invention

The anti-viral activity of compounds of the present set of claims was observed in cell culture and is thus unequivocally a direct anti-viral activity and not due to any supposed immunomodulatory activity of the compounds. Accordingly, the references cited by the Examiner that relate to cytokine inducers and other interferon activity are not relevant to the

present claims because such effects rely on immunomodulatory activity which was clearly not involved in the observed activity of the claimed compounds.

#### Selectivity of the Present Claimed Compounds

The anti-viral activity of the various endoperoxide compounds of the present invention and the cited prior art are presented in the following table (no entry or blank cell means the compound(s) was not tested against the listed virus).

|                      | Anti-viral Activity |     |     |     |     |      |     |     |      |
|----------------------|---------------------|-----|-----|-----|-----|------|-----|-----|------|
|                      | Compound            | Flu | CMV | HSV | HIV | Buny | FLV | VSV | BVDV |
| Qian                 | Qinghasu            | +   |     |     |     |      |     |     |      |
| Efferth              | Artensuate          | -   | +   | +   | ±   |      |     |     |      |
| Zhiang               | Artemether          |     |     |     |     | +    |     |     |      |
| Venugopalan          | Novel cpds          |     |     |     |     |      | +   |     |      |
| Present<br>Invention | Artemisinin         |     | ±   | -   | -   |      |     | ±   | +    |

The Examiner takes the position that various endoperoxides are broad spectrum anti-virals. However, only Efferth and the present invention screened for activity against more than one virus and both demonstrate selectivity of the compounds' anti-viral activity, not the broad spectrum activity asserted by the Examiner. Once again, it is important to note that the present invention employed only *in vitro* systems where activity must be due to a direct anti-viral effect and not due to any immunomodulatory activity of the compounds.

The Section 103(a) rejections of pending claims 1-2 and 5-6 should be reconsidered and withdrawn.

Accordingly, the purpose of the claimed invention is not taught nor suggested by the cited references, nor is there any suggestion or teaching which would lead one skilled in the relevant art to combine the references in a manner which would meet the purpose of the claimed invention. Because the cited references, whether considered alone, or in combination with one

another, do not teach nor suggest the purpose of the claimed invention, Applicant respectfully submits that the claimed invention, as amended, patentably distinguishes over the prior art, including the art cited merely of record.

Based on the foregoing, Applicant respectfully submits that its claims 1-2 and 5-6 are in condition for allowance at this time, patentably distinguishing over the cited prior art. Accordingly, reconsideration of the application and passage to allowance are respectfully solicited.

The Examiner is respectfully urged to call the undersigned attorney at (515) 288-2500 to discuss any remaining issues that may exist or arise.

Respectfully submitted,

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